



## CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2023-0032]

### Notice of availability: Proposed Supplemental Guidance for CPSC Chronic Hazard Guidelines

**AGENCY:** U.S. Consumer Product Safety Commission.

**ACTION:** Notice of availability and request for comment.

**SUMMARY:** The Consumer Product Safety Commission (Commission or CPSC) is announcing the availability of proposed supplemental guidance for its Chronic Hazard Guidelines. The supplements are draft supplemental guidance for the use of benchmark dose methodology in risk assessment, and draft supplemental guidance for the analysis of uncertainty and variability in risk assessment. The Commission requests comments from the public on the proposed supplemental guidance.

**DATES:** Submit comments by [INSERT DATE **60 DAYS** AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You can submit comments, identified by Docket No. CPSC-2023-**0032** by any of the following methods:

*Electronic Submissions:* Submit electronic comments to the Federal eRulemaking Portal at [www.regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. CPSC typically does not accept comments submitted by electronic mail (email), except as described below.

*Mail/Hand Delivery/Courier/Confidential Written Submissions:* CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer

Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479.

*Instructions:* All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided to [www.regulations.gov](http://www.regulations.gov). If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov).

*Docket:* For access to the docket to read background documents or comments received, go to [www.regulations.gov](http://www.regulations.gov), and insert the docket number, CPSC-2023-0032 into the “Search” box, and follow the prompts. The proposed supplemental guidance is available under “Supporting and Related Material.” It is also available on the Commission’s website at: [https://www.cpsc.gov/Newsroom/FOIA/ReportList?month=07&year=2023&nfr\\_type=commission&title](https://www.cpsc.gov/Newsroom/FOIA/ReportList?month=07&year=2023&nfr_type=commission&title), and from the Commission’s Office of the Secretary.

**FOR FURTHER INFORMATION CONTACT:** Eric Hooker, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2516; email: [ehooker@cpsc.gov](mailto:ehooker@cpsc.gov).

## **SUPPLEMENTARY INFORMATION:**

### **A. Background**

In 1992 the Commission issued guidelines for assessing chronic hazards under the Federal Hazardous Substances Act (FHSA), including carcinogenicity, neurotoxicity, reproductive/developmental toxicity, exposure, bioavailability, risk assessment, and acceptable risk. .

Determining whether a product is or contains a hazardous substance involves scientific analysis, legal interpretation, and the application of policy judgment. The Guidelines are intended to assist firms in identifying products that present chronic hazards, to meet their

labeling obligations under the FHSA and the Labeling of Hazardous Art Materials Act (LHAMA). They are not binding on industry or the Commission. Indeed, chronic toxicity may be established in various ways. The Commission may determine that a product is a hazardous substance due to a chronic hazard based on any evidence that is relevant and material to such a determination.

For example, peer-reviewed scientific studies by third parties and toxicity assessments from CPSC's peer agencies may be relevant and material evidence to establish chronic toxicity and that a substance is a "hazardous substance" under the FHSA. Likewise, evidence from third parties may be useful to determine chronic toxicity. For instance, third party studies may indicate that chronic adverse health effects are associated with foreseeable levels of consumer exposure, allowing the Commission to conclude that the FHSA's criteria for a "hazardous substance" are satisfied. Other cases, however, may require CPSC to undertake original research to fill gaps in knowledge.

In addition, while the Guidelines describe certain toxic endpoints, they do not limit the toxic endpoints the Commission may consider. The Commission may consider all forms of personal injury or illness as potential toxic endpoints.

The chronic hazard guidelines, which should be understood as a set of best practices, are not mandatory for the Commission or for stakeholders. The guidelines describe methods that CPSC staff may use to assess chronic hazards under the FHSA. Furthermore, the guidelines are intended to be sufficiently flexible to incorporate the latest scientific information, such as advances in risk assessment methodology. Risk assessors may deviate from the default assumptions described in the guidelines, provided that their methods and assumptions are documented, scientifically defensible, and supported by appropriate data as indicated in section VI.A.2 of the preamble of the guidelines. However, given that the guidelines represent an available set of best practices, risk assessors are encouraged to use the information and approaches outlined therein where appropriate.

In the years since the guidelines were issued, there have been numerous advances in the basic science underlying the guidelines, such as the use of transgenic animals to elucidate mechanisms of carcinogenicity and toxicity. There also have been several changes in the practice of risk assessment, including wider acceptance and use of risk assessment methods such as the benchmark dose approach and probabilistic exposure assessment. Therefore, CPSC is proposing two guidance documents to supplement the 1992 guidelines.<sup>1</sup>

The first supplement provides guidance for the application of benchmark dose methodology (BMD) to risk assessment. This supplement discusses an alternative to the traditional approach described in the original guidelines for estimating acceptable daily intakes (ADIs) for carcinogenic and other hazards, such as neurotoxicological or reproductive/developmental hazards. The second supplement is guidance for the analysis of uncertainty and variability, including use of probabilistic risk assessment methodology, which is most relevant to exposure assessment.

Like the 1992 guidelines, the proposed supplemental guidance documents are not mandatory. Rather, they describe methods that CPSC staff and manufacturers may use to evaluate chronic hazards. The guidelines are intended to assist manufacturers in complying with the requirements of the FHSA and to facilitate the use of reliable risk assessment methodologies by both manufacturers and CPSC staff.

## **B. Request for comments**

The Commission invites comments on the proposed guidance supplementing CPSC's Chronic Hazard Guidelines with respect to the use of benchmark dose methodology in risk assessment and analysis of uncertainty and variability in risk assessment.

The CPSC will consider all timely comments before finalizing the supplemental

---

<sup>1</sup> The proposed guidance documents are available at: [https://www.cpsc.gov/s3fs-public/Federal-Register-Notice-of-Availability-of-Proposed-Supplemental-Guidance-for-CPSC-Chronic-Hazard-Guidelines.pdf?VersionId=dzserzX2mvO8.sO\\_Q7Thdcb8YufASlSr](https://www.cpsc.gov/s3fs-public/Federal-Register-Notice-of-Availability-of-Proposed-Supplemental-Guidance-for-CPSC-Chronic-Hazard-Guidelines.pdf?VersionId=dzserzX2mvO8.sO_Q7Thdcb8YufASlSr).

guidance. Comments should be submitted by **[Insert date 60 days after date of publication in the Federal Register]**. Information on how to submit comments can be found in the ADDRESSES section of this notice.

Authority: 15 U.S.C. 2079(a); 15 U.S.C. 1261; 15 U.S.C. 1277.

---

Alberta E. Mills,  
Secretary,  
Consumer Product Safety Commission.

[FR Doc. 2023-16844 Filed: 8/23/2023 8:45 am; Publication Date: 8/24/2023]